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10/661,742	09/12/2003	Eva Rojer	Strom.7274	9486

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,742	ROJER, EVA	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *1-30,32-36,38,40 and 42-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,37,39,41 and 45-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/27/06 & 9/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Rojer

1. Applicant's election with traverse of Group XIII (Claims 31, 37, 39 and 41) in the reply filed on 10/2/07 is acknowledged. The traversal is on the ground(s) that under Article 27 of the Patent Cooperation Treaty, there was no such restriction required in the International application from which the subject application claims priority. Thus with reference to the unity of the invention there is only one invention and all of the claims should be examined together. This is not found persuasive because the instant case is not a national stage filing of an international application (i.e. 35 U.S.C. 371) and therefore the standard of the unity of the invention is not applied. The claims of the instant application as indicated in the last office action includes multiple patentably distinct inventions, and search these distinct invention will impose serous search burden. Therefore, the restriction is deemed proper and is therefore made FINAL.

2. In the response filed on 10/2/07, applicants failed to correctly elect species as required in the office action mailed on 9/4/07. During a telephone conversation with applicant's representative Arlene J. Powers on 11/13/2007, a provisional election of species: coded by exon 2-7 of SCCA1 gene fused to exon 8 of SCCA2 gene for group (a), and coded by exon 2-7 of SCCA2 gene fused to exon 8 of SCCA1 gene for group (b) was made without traverse. Affirmation of this election must be made by applicant in replying to this Office action.

3. Applicant's amendment to the claims to insert SEQ ID NO filed on 12/12/2007 is acknowledged.

4. Claims 1-50 are pending. New claims 45-50 have been added. Claims 1-30, 32-36, 38, 40, and 42-44 are withdrawn from further consideration as being drawn to non-elected inventions.

5. Claims 31, 37, 39, 41, and 45-50 are under examination. Due to species election, claims 31, 37, 39, 41 and 45-50 are examined to the extent that the SCCA1/SCCA2 fusion protein is encoded by the exons 2-7 of the SCCA1 gene fused to exon 8 of the SCAA2 gene, i.e. SEQ ID NO.1.

Priority

6. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Sweden on 3/15/2001. It is noted, however, that applicant has not filed a certified copy of the Sweden 0100938-0 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

7. The information disclosure statement (IDS) filed on 6/27/2006 has been considered. A signed copy is attached hereto.

8. The information disclosure statement filed 9/12/2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent, publication, or other information listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been

considered as to the merits as it pertains to the foreign prior art DE 19742725A1 which is in German.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Drawings

9. The Drawings filed on 1/20/04 are objected to because of the following informality. The label for the X-axis in Figure 8 is not in English.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

10. The disclosure is objected to because of the following informality.

A. The Brief Description of the Drawings does not reference Figure 1A, 1B and 1C.

B. The Brief Description of Drawing is not consistent of the Drawing. For example, Figure 6 is the nucleotide sequence of SCCA2/SCCA1, and Figure 7 is the amino acid sequence of SCCA2/SCCA2. However, the Brief Description of Drawing for Figure 6 and Figure 7 is Titer of PABan to SCC antibody, and reactivity of established hydridomas with different SCC antigens, respectively (see specification page 16 and the amendment to the specification filed on 6/4/07. The Brief Description of Drawings for Figure 6-9 appears to be for Figure 8-10.

C. The details mentioned in the Brief Description of Drawings are not shown in the Drawings. For example, the Description of Figure 3 mentions Boxes, dotted lines, which are not found in Figure 3.

D. The Brief Description of Drawings mentions Figure 9, a Southern blot analysis, which is not found in Drawing.

E. The meaning of the term "PABan" cited in the Description for Figure 6 is unclear. The specification does not define this term. Moreover, the term "PABan" does not have a well-recognized meaning in the art.

F. The Figures referred in the specification, for example, page 25, lines 27 and 29, page 9, line 29, are inconsistent with the Drawings. Applicant is required to correct the inconsistency found throughout the specification.

G. The first line of the specification should be updated if applicant desires priority under 35 U.S.C. 1 19(e), 120, 121 and 365(c) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application (s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No.___" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date 6f the parent application.

To obtain benefit under 35 U.S.C. 120 and 365(c) of a prior international application designating the U.S., the continuing application must:

(A) include a specific reference to the prior international application (either in the application data sheet (37 CFR 1.76) or in the first sentence(s) of the specification),

(B) be copending with the prior international application, and

(C) have at least one inventor in common with the prior international application.

With regard to (A), the specific reference to the international application required under 35 U.S.C. 120 and 365(c) must either be contained in the first sentence(s) of the specification following the title or included in an application data sheet. 37 CFR 1.78(a)(2)(iii). The specific reference must identify the parent international application by international application number and international filing date and indicate the relationship of the applications (i.e., continuation, continuation-in-part, or division). See 37 CFR1.78(a)(2)(i)) and MPEP § 201.11. An example of an appropriate first sentence of the specification is, for example, "This is a continuation of International Application PCT/EP2004/000000, with an international filing date of January 5, 2004, now abandoned." See MPEP1895.01.

Appropriate correction is required.

Claim Objections

11. Claim 31, 37, 39, 41 and 45-50 are objected to because of the following informalities:

A. Claims 31, 49 and 50 are objected to for reciting the term "SCCA1/A2" in claim 31. This term is not consistent with the term "SCCA1/SCCA2" recited in other claims. Appropriate correction is required.

B. Claim 37, and 47-48 are objected to because it is unclear what is being claimed. Is it a product or is it a method/process?

C. Claims 39, 41, 45 and 46 are objected to because the phrase "by detecting the SCCA2/SCCA1 fusion protein" is in the body of the preamble of the process. If the phrase is intended for the preamble, the claims lack active steps.

D. Claim 41 is objected to for reciting the phrase "wherein the fusion protein is used in a histochemical analysis". Claim 39, from which claim 41 is dependent, only recites "detecting the SCCA2/SCCA1 fusion protein". Therefore, the meaning of the term "used" is not clear.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112, 2nd paragraph & - 35 USC § 101

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

13. Claims 31, 37, and 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 37, and 47-50 provide for the use of Western blotting (see claim 31 for example) and antibody (see claim 37 for example), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

MPEP states "Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph. For example, a claim which read: "A process for using monoclonal antibodies of claim 4 to isolate and purify human fibroblast interferon." was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Ex parte Erlich, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986)". See MPEP 2173.05(q).

14. Claims 31, 37, and 47-50 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, 1st paragraph

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claims 39, 41, 45 and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing the presence or absence of a squamous cell carcinoma in a human comprising detecting SCCA1 protein or SCCA2 protein in a sample of said human, does not reasonably provide enablement for a method for diagnosing the presence or absence of a squamous cell carcinoma in a human comprising detecting the SCCA1/SCCA2 fusion protein in a sample of said human. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

Claims are drawn to a method for diagnosing the presence or absence of a squamous cell carcinoma in a human comprising detecting the SCCA1/SCCA2 fusion protein in a sample of said human.

Working Examples and Guidance in the Specification

The specification teaches that the mRNA encoding the fusion protein SCCA1/SCCA2 consisting of SEQ ID NO.1 was detected by sequencing cDNAs obtained from squamous cell carcinoma (SCC) cell lines (see specification, page 3, lines 22-23, page 4, last section).

The specification does not disclose that the SCCA1/SCCA2 fusion protein naturally exists. The specification does not show that the SCCA1/SCCA2 fusion protein is differentially expressed in SCC cells as compared to normal cells, and is correlated to the presence of SCC.

The state of the prior art and the predictability or lack thereof in the art:

Schick et al. (PNAS, 1998, 95: 13465-13470, IDS) disclosed a SCCA1/SCCA2 fusion protein, wherein the fusion protein (reactive site loop swaps between SCCA1 and SCCA2) was made recombinantly (artificially) for the purpose of studying the substrate specificity of SCCA1 and SCCA2 (see abstract).

Post filing reference by Roijer et al. (Tumor Biol. 2003, 24:46-52) discloses that the SCCA1/SCCA2 transcripts were detected in the SCC cell lines.

There is no indication in the art that the SCCA1/SCCA2 fusion protein is actually expressed in any cells including SCC cells.

In the absence of any disclosed relationship between the claimed fusion protein and any SCC, any information obtained from mRNA expression would only serve as the basis for further research on the observation itself. Those of skill in the art, recognize that expression of mRNA, specific for a tissue type, does not necessarily correlate nor predict equivalent levels of polypeptide expression. Greenbaum et al. (Genome Biology, 2003, Vol. 4, Issue 9, pages 117.1-117.8) cautions against assuming that mRNA levels are generally correlative of protein levels. The reference teaches (page 117.3, 2nd column) that primarily because of a limited ability to measure protein abundances, researchers have tried to find correlations between mRNA and the limited protein expression data, in the hope that they could determine protein abundance levels from the more copious and technically easier mRNA experiments. To date, however, there have been only a handful of efforts to find correlations between mRNA and protein expression levels, most notably in human cancers and yeast cells. And, for the most part, they have reported only minimal and/or limited correlations. The reference further teaches (page 117.4, 2nd column) that there are presumably at least three reasons for the poor correlations generally reported in the literature between the level of mRNA and the level of protein, and these may not be mutually exclusive. First, there are many complicated and varied post-transcriptional mechanisms involved in turning mRNA into protein that are not yet sufficiently well defined to be able to compute protein concentrations from mRNA; second, proteins may differ substantially in their *in vivo* half

lives; and/or third, there is a significant amount of error and noise in both protein and mRNA experiments that limit our ability to get a clear picture. The reference further notes (page 117.6, page 2nd column) that to be fully able to understand the relationship between mRNA and protein abundances, the dynamic processes involved in protein synthesis and degradation have to be better understood. For example, Alberts et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) illustrate post-transcriptional regulation of ferritin wherein the translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferrin receptor polypeptide is translated. Also, with regards to tumor associated antigens, Fu et al. (EMBO Journal, 1996, Vol. 15, pp. 4392-4401) teach that levels of p53 protein expression do not correlate with levels of p53 mRNA levels in blast cells taken from patients with acute myelogenous leukemia, said patients being without mutations in the p53 gene. Furthermore, Mallampalli et al. (Biochem. J. 1996, Vol. 318, pages 333-341) teach that the glucocorticoid, betamethasone, increased mRNA expression of cholinephosphate cytidylyltransferase (CT) as determined by RT-PCR and Southern analysis, but did not alter the levels of the CT enzyme as assayed by Western blotting (abstract, and page 339, 2nd column, 2nd paragraph). Thus, the predictability of protein translation and its possible utility as a diagnostic or therapeutic are not necessarily contingent on the levels of mRNA expression due to the multitude of homeostatic factors affecting transcription and translation.

Therefore, absent evidence of the protein's expression including the correlation to a diseased state, one of skill in the art would not be able to predictably use the protein for diagnosis of any cancer without undue experimentation.

Breadth of the claims

Claims encompass a method for diagnosis of SCC in a human comprising detecting the SCCA1/SCCA2 fusion protein in a sample of said human. The sample can be any samples, including tissue and various body fluids.

Quantity of experimentation

In view of the unpredictability of protein expression including the correlation to any cancer, it would require undue experimentation to use the SCCA1/SCCA2 fusion protein for diagnosis of squamous cell carcinoma.

Level of skill in the art

The level of the skill in the art is deemed to be high

Conclusion:

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of the art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example which shows the SCCA1/SCCA2 fusion protein is differentially

expressed in SCC as compared to normal and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 31, 37, 39, and 45-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Nawata et al. (Electrophoresis, 1999, 20: 614-617).

Due to indefinite nature of claims 31, 37, and 47-50 (see paragraph 13 above), and the lacking of active steps of claims 39, 45 and 46 (see paragraph 11 above), claims are interpreted as a method for detection the fusion protein SCCA1/SCCA2 using Western blotting, or immunoassay, and a method for diagnosis of the presence or absence of a squamous cell carcinoma in a human comprising contacting a sample obtained from said human with a monoclonal or polyclonal antibody, and detecting the complex formed between said antibody and said fusion protein SCCA1/SCCA2, wherein said SCCA1/SCCA2 fusion protein consists of SEQ ID NO.1.

Nawata et al. teach a method for detection of SCCA1, and/or SCCA2 in squamous cell carcinoma tissue by 2D-electrophoresis and Western blotting using a

monoclonal antibody specific for SCC antigen (which detects both SCCA1 and SCCA2). (page 615). Because Nowata et al. teach contacting squamous cell carcinoma tissue with an antibody that is specific for SCCA1 and SCCA2 proteins, and detecting the complex formed between the antibody and the SCCA1 and SCCA2 proteins, and because the antibody of Nawata et al. would also bind to the claimed SCCA1/SCCA2 fusion protein (i.e. SEQ ID NO.1), by performing the detection of Nawata et al, one would have detected the SCCA1/SCCA2 fusion protein if the fusion protein was expressed in squamous cell carcinoma as asserted by the instant specification.

19. Claims 37, 39, 41, and 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuda et al. (Cancer, 1990, 65: 2261-2265).

Due to indefinite nature of claims 31, 37, and 47-50 (see paragraph 13 above), and the lacking of active steps of claims 39, 45 and 46 (see paragraph 11 above), claims are interpreted as a method for detection the fusion protein SCCA1/SCCA2 using immunoassay, and a method for diagnosis of the presence or absence of a squamous cell carcinoma in a human comprising contacting a sample obtained from said human with a monoclonal or polyclonal antibody, and detecting the complex formed between said antibody and said fusion protein SCCA1/SCCA2, wherein said SCCA1/SCCA2 fusion protein consists of SEQ ID NO.1, said fusion protein is detected by histochemical analysis.

Matsuda et al. teach immunohistochemical detection of squamous cell carcinoma-related antigen (SCC-Ag) in esophageal squamous cell carcinoma tissue by

immunohistochemistry using anti-SCC-Ag mouse gammaglobulin. Because Matsuda et al. teach contacting squamous cell carcinoma tissue with an antibody that is specific for SCC-Ag, and detecting the complex formed between the antibody and the SCC-Ag, and because the antibody of Matsuda et al. would also bind to SCCA1/SCCA2 fusion protein (i.e. SEQ ID NO.1), by performing the detection of Matsuda et al, one would have detected the SCCA1/SCCA2 fusion if the fusion protein was expressed in squamous cell carcinoma as asserted by the instant specification.

20. Claims 37, 39, and 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Cataltepe et al. (Clin. Chim. Acta, 2000, 295:107-127).

Due to indefinite nature of claims 31, 37, and 47-50 (see paragraph 13 above), and the lacking of active steps of claims 39, 45 and 46 (see paragraph 11 above), claims are interpreted as a method for detection the fusion protein SCCA1/SCCA2 using immunoassay, and a method for diagnosis of the presence or absence of a squamous cell carcinoma in a human comprising contacting a sample obtained from a squamous cell carcinoma patient with a monoclonal or polyclonal antibody, and detecting the complex formed between said antibody and said fusion protein SCCA1/SCCA2, wherein said SCCA1/SCCA2 fusion protein consists of SEQ ID NO.1.

Cataltepe et al. teach detection of tumor markers SCCA1 and SCCA2 by immunoassay such as ELISA in plasma samples from patients with squamous cell carcinomas of the head and neck region using monoclonal antibody (see page 109, and page 119, last paragraph). Cataltepe et al. teach detection of SCCA1 and SCCA2

using a polyclonal antibody (page 108, lines 14-15, and last paragraph, line 2). Because Cataltepe et al. teach contacting a sample obtained from a squamous cell carcinoma subject with an antibody that is specific for SCCA1, and/or SCCA2 protein, and detecting the complex formed between the antibody and the SCCA and/or SCCA2 protein, and because the antibody of Cataltepe et al. would also bind to the SCCA1/SCCA2 fusion protein (i.e. SEQ ID NO.1), by performing the detection of Cataltepe et al., one would have detected the SCCA1/SCCA2 fusion if the fusion protein was expressed in squamous cell carcinoma as asserted by the instant specification.

Conclusion

21. No claims are allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang

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Art Unit 1643
1/29/08